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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/945,144	01/20/1998	MICHEL LEBRUN	RP/PCT	2339

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/945,144

Applicant(s)

LEBRUN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 16 October 2001 has been entered.
2. Claims 36-41 have been cancelled.
3. Claims 42-53 have been added.
4. The Abstract filed 16 October 2001 has been entered into the file.
5. The "Appendices 1-11 to Amendment (Rule 116)" filed 16 October 2001 has been noted.

Claim Rejections - 35 USC § 101

6. Claim 44 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. A nucleic acid having the sequence of SEQ ID NO: 4 reads on a product of nature, and as such is non-statutory subject matter. To obviate this rejection, the claim should read -- An isolated polynucleotide molecule having... --.

Claim Objections

7. Claims 43, 46, 48, 49, 51 and 52 are objected to because of the following informalities:

At claim 43, the phrase "A nucleic acid molecule" should read -- The nucleic acid molecule -- in referring to the molecule of claim 42.

At claim 46 line 1, the phrase "A vector" should read -- The vector -- in referring to the vector of claim 45.

At claims 48 and 49, the phrase "A plant cell" should read -- The plant cell -- in referring to the cell of claim 47.

At claims 51 and 52, the phrase "A transgenic plant" should read -- The transgenic plant -- in referring to the plant of claim 50.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 42, 50 and 53 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, because it is unclear from the instant specification if all nucleic acid molecules of plant origin encoding an EPSPS enzyme have a threonine at amino acid position 102 and a proline at amino acid position 106, one of skill in the art would not know to which nucleic acid molecules the claim are directed and thus the metes and bounds of the claimed invention.

10. Claims 42, 50 and 53 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "of mature EPSPS

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sequence" is indefinite as to which sequence the limitation is referring. It is suggested that the phrase be amended to read -- of a mature plant EPSPS sequence --.

11. Claim 47 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "of mature EPSPS sequence" is indefinite as to which sequence the limitation is referring. It is suggested that the phrase be amended to read -- of a mature maize EPSPS sequence --.

12. Claims 48, 49, 51 and 52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "increased tolerance" is relative and does not state the metes and bounds of the claimed invention. Appropriate correction is required.

13. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 42 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, Applicant has only described a modified maize EPSPS encoding polynucleotide having the claimed modification. Applicant does not describe any other plant EPSPS encoding

polynucleotides having the claimed modifications. Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

In addition, see *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself".

15. Claims 42, 45, 46 and 50-53 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of maize origin encoding a modified 5-enolpyruvylshikimate-3-phosphate synthase having the claimed modifications, vectors, transgenic plants and plant cells comprising said DNA sequence, and a method of protecting plants comprising said transgenic plants, does not reasonably provide enablement for all isolated polynucleotides of plant origin encoding a modified 5-enolpyruvylshikimate-3-phosphate synthase having the claimed modifications, vectors, transgenic plants and plant cells comprising said DNA sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in

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scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 June 2001. Applicant's arguments filed 16 October 2001 have been fully considered but they are not persuasive.

Applicant argues that the specification states expressly that the modified DNA molecule may be of plant origin (page 4, lines 13-14 of the Remarks). Applicant argues that the domain of the EPSPS enzyme overlapping relative positions 102 to 106 (of the maize sequence) has been recognized in the prior art as being highly conserved in plants (page 4, lines 24-25 of the Remarks). In addition, Applicant argues that the prior art teaches that EPSPS enzymes in plant species have significant similarity, citing USP 5,310,667, figure 1a-b, and that it would not have required undue trial and error experimentation for one of ordinary skill in the art to isolate all DNA sequences encoding an EPSPS gene and modify them as claimed (pages 5-6 of the Remarks).

The Examiner responds, that the statement of intent to modify other plant DNA molecules does not necessarily enable the specification within the scope of the instant claimed invention. It is noted that Applicant claims modification of an EPSPS enzyme at positions 102 and 106, not relative positions. In addition, Applicant's reliance upon the teachings of others directed to different mutations of the EPSPS enzyme is irrelevant.

The '667 patent teaches modification of the petunia, tomato, *Brassica* and maize genes encoding the same modification and producing the same glyphosate tolerance.

Applicant has only taught that modification at positions 102 and 106 of the maize EPSPS enzyme produces a glyphosate tolerant enzyme.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3482.


GARY BENZION
PRIMARY EXAMINER

David H. Kruse, Ph.D.
9 November 2001